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EXAMINER	
VU, JAKE MINH	
ART UNIT	**PAPER NUMBER**
1618	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/663,238	KHAIAT ET AL.	
	Examiner	Art Unit	
	Jake M. Vu	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/10/04, 2/17/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of Applicants' Information Disclosure Statements filed on 12/10/04 and 2/17/05. Claims 1-27 are pending in the instant application.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4, 8-12, 16-19, 24, and 27 are provisionally rejected on the ground of nonstatutory double patenting over copending Application No. 10/340341. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follow:

A method for inhibiting or treating oily skin and the consequences thereof, such as acne, by using a composition comprising of a sebum regulating agent, a keratolytic agent, and an anti-inflammatory agent.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-19 and 24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification, while being enabling for the control or inhibition of oily/shiny skin or acne, does not reasonably provide enablement for the prevention of the oily/shiny skin appearance, or for the prevention of consequential disorders of oily/shiny skin appearance, such as acne. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Enablement is considered in view of the Wands factors (MPEP 2164.01 (a)). These include: (1) breadth of the claims; (2) nature of the invention; (3) state of the prior art; (4) amount of direction provided by the inventor; (5) the level of predictability in the art; (6) the existence of working examples; (7) quantity of experimentation needed to make or use the invention based on the content of the disclosure; and (8) relative skill in the art. All of the factors have been considered with regard to these claims, with the most relevant factors discussed below:

1) The breadth of claims: The complex nature of the subject matter of this invention is greatly exacerbated by the breadth of the claims. The claimed invention includes the prevention of oily/shiny skin appearance as well as the prevention of all disorders that arise from the oily/shiny appearance of skin. The term "prevention" indicates a claim whereby those normally not at risk for developing such a condition would be prevented from ever developing the condition with the composition being claimed.

2) The nature of the invention: The invention is drawn to a method of preventing, controlling or inhibiting oily/shiny skin and consequential disorders that arise from the oily/shiny appearance of skin.

3) The state of the prior art: The state of the art regarding the inhibition or control of oily/shiny skin and consequential disorders thereof is well developed. However, the state of the art regarding the prevention of oily/shiny skin or disorders arising therefrom, such as for example acne, is underdeveloped (see for example "Optimal Management of Acne to Prevent Scarring and Psychological Sequelae" to Alison M. Layton, Am. J. Clin. Dermatol. 2001; 2(3): 135-141.) Layton describes how acne vulgaris is a common inflammatory dermatosis in which multiple factors are involved, including an increase in sebum production and the proliferation of bacteria (see abstract, in particular.) Layton describes how treatment should be aimed at achieving clearance of acne and prevention of scarring (see page 137, section 4, in particular.) Thus, Layton shows that it is known to clear pre-existing acne, but the complete prevention of acne such that it never occurs is not known. Furthermore, Layton teaches that to date there is no

effective topical therapy that will control sebum production (see page 137, section 5, in particular), and thus the control of factors that contribute to the oily/shiny appearance of skin, such as sebum production, are not known.

Reasonable guidance with respect to preventing the oily/shiny appearance of skin and consequential disorders thereof relies on quantitative analysis from defined populations that have been successfully pre-screened and are predisposed to such conditions. This type of data might be derived from widespread genetic analysis, family histories, correlation of genetic and environmental factors, etc. The essential element towards the validation of a preventive therapeutic is the ability to test the therapeutic on subjects monitored in advance of the onset of oily/shiny skin appearance or disorder arising therefrom, and link those results with subsequent histological confirmation of the presence or absence of oily/shiny skin and disorders. This irrefutable link between antecedent drug and subsequent knowledge of the prevention of the condition is the essence of a valid preventive agent. As the correlation among factors contributing to oily/shiny skin appearance and skin disorders arising therefrom, such as acne, are not known, the state of the art does not provide a reasonable method of making such a predictive analysis. Further, a preventive administration also must assume that the therapeutic will be safe and tolerable for anyone susceptible to the condition or disease.

4) The amount of direction provided by the inventor: The guidance of the specification as to "prevention" of oily/shiny appearance of skin or consequential disorders therefrom is completely lacking. Applicants' specification shows the reduction of sebum levels by treating with Applicants' compositions, but does not show that the

reduction is sufficient or maintained for a long enough time to provide the prevention of the oily/shiny appearance of skin, and also does not show that the reduction is sufficient to prevent all disorders arising from the shiny/oily appearance of skin. It is furthermore noted that the test subjects in these examples were selected as exhibiting high sebum levels before the onset of testing, and thus the oily/shiny appearance of skin was not prevented in these individuals because the individuals already exhibited the high sebum levels associated with oily/shiny skin appearance. The specification also does not provide any alternative models by which the prevention of the oily/shiny appearance of skin or disorders arising therefrom could be assessed.

5) Predictability of the art: The invention is directed to the control, inhibition or prevention of the oily/shiny appearance of skin and consequential disorders thereof in general with a composition having a sebum regulator, an anti-inflammatory agent, and a keratolytic agent. It is well established that "the scope of enablement varies inversely with the degree of unpredictability of the factors involved," and physiological activity is generally considered to be an unpredictable factor. See *in re Fisher*, 427 F.2d 833, 839 (1970.)

It should also be noted that one of ordinary skill in the art would recognize that it is highly unpredictable in regard to what population will experience a skin disorder such as the oily/shiny appearance of skin or disorders such as acne, as discussed in above. In order to administer the agent to the population at large, one would need to consider the therapeutic effects, side effects and especially potential serious toxicity that may be generated by drug-drug interactions as a result of administration of the claimed

compounds to a living organism (e.g., an animal.) It is furthermore highly unpredictable whether a skin disorder involving oily/shiny appearance of skin could be prevented, as the state of the art as given by Layton shows that the control of such factors as sebum production that contribute to oily/shiny skin appearance are not known.

6) The presence or absence of working examples: Applicants have only shown examples for the decrease of sebum levels. Applicants have not shown examples for the complete prevention of the oily/shiny appearance of skin or the prevention of disorders that are a consequence of such oily/shiny skin appearance.

7) The quantity of experimentation: In order to practice the disclosed invention, one would need to undergo experimentation to test Applicants' compositions such as those claimed to determine whether or not any of them are actually capable of completely preventing the oily/shiny appearance of skin, and disorders resulting therefrom, as the instant specification does not show the complete prevention thereof.

As discussed above, the specification fails to provide sufficient support for determining all individuals susceptible to oily/shiny skin or skin disorders resulting therefrom to allow one or ordinary skill in the art to administer to a population the compositions of the instant invention for the prevention of oily/shiny skin and consequential disorders in general. As a result, one of ordinary skill in the art would be forced to perform an exhaustive search for the population that is susceptible to oily/shiny skin and consequential disorders resulting therefrom to use the instant invention.

Genentech, 108 F.3d at 1366 states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

8) The relative skill of those in the art: the skill of one of ordinary skill in the art is high, e.g. Ph.D. and M.D. level skill.

The totality of these eight factors clearly shows Applicants' lack of enablement to prevent oily/shiny skin and consequential disorders that arise from the oily/shiny appearance of skin. Thus, the Examiner suggests deleting the reference to "preventing" in the claims. For examination purposes, the Examiner is interpreting the claims as drawn to a method of inhibiting or controlling the oily/shiny appearance of skin and consequential disorders resulting therefrom.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 8-12, 16-19, 24, and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Khaiat et al (W 02/05773).

Applicants' claims are directed to a method of controlling and/or inhibiting the oil nature of skin and consequences thereof, by applying a composition comprising of: a

sebum regulator; an anti-inflammatory compound; a keratolytic agent; bacterial lipase inhibitor; and a bacterial proliferation inhibitor.

Khaiat disclosed a method of controlling and/or inhibiting the oil nature of skin and consequences thereof (claim 3), by applying a composition comprising of: a sebum regulator, such as cedarwood extract (pg. 5, line 6-13); an anti-inflammatory compound, such as allantoin or alpha-bisabolol (pg. 8, line 19-22); a keratolytic agent, such as salicylic acid (pg. 17); bacterial lipase inhibitor, such as cedarwood extract (pg. 6, line 1-10); and a bacterial proliferation inhibitor, such as salicylic acid (pg. 17).

Note, in claim 27, the method of the claimed composition "whereby the appearance of said skin improves within two days of said topical application" has not been given patentable weight, because the prior art compositions would be inherently capable of performing said method.

Claims 1-7, 9-11, 12-15, 17-19, 24 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by De Paoli (EP 1269991).

Applicants' claims are directed to a method of controlling and/or inhibiting the oil nature of skin and consequences thereof, by applying a composition comprising of: a sebum regulator; an anti-inflammatory compound; a keratolytic agent; bacterial lipase inhibitor; and a bacterial proliferation inhibitor.

De Paoli disclosed a method of controlling and/or inhibiting the oil nature of skin and consequences thereof, by applying a composition comprising of: a sebum regulator, such as linoleic acid [0026] or caprylol glycine [0020], [0048]; an anti-inflammatory

compound, such as triethyl citrate [0026](part 2); a keratolytic agent, such as salicylic acid [0020]; bacterial lipase inhibitor [0029]; and a bacterial proliferation inhibitor, such as salicylic acid [0020].

Note, in claim 27, the method of the claimed composition "whereby the appearance of said skin improves within two days of said topical application" has not been given patentable weight, because the prior art compositions would be inherently capable of performing said method.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Khaiat et al (cited supra) in view of De Paoli (cited supra), Chan et al (*The analgesic and anti-inflammatory effects of Portulaca oleracea L. subsp. Sativa (Haw.) Celak. J Ethnopharmacol. 2000 Dec; 73(3):445-51.*), and Malton et al (US 6,893,647).

Applicants' claims are directed to a method of controlling and/or inhibiting the oil nature of skin and consequences thereof, by applying a composition comprising of: a sebum regulator, such as a glycine derivative; an anti-inflammatory compound, such as

portulaca extract; a keratolytic agent; bacterial lipase inhibitor; bacterial proliferation inhibitor; and a fragrance such as cinnamon extract.

As discussed above, Khaiat teaches a method of controlling and/or inhibiting the oil nature of skin and consequences thereof (claim 3), by applying a composition comprising of: a sebum regulator, such as cedarwood extract (pg. 5, line 6-13); an anti-inflammatory compound, such as allantoin or alpha-bisabolol (pg. 8, line 19-22); a keratolytic agent, such as salicylic acid (pg. 17); bacterial lipase inhibitor, such as cedarwood extract (pg. 6, line 1-10); a bacterial proliferation inhibitor, such as salicylic acid (pg. 17); and a fragrance (pg. 9, line 12).

However, Khaiat does not specifically teach using: a sebum regulator, such as a glycine derivative; an anti-inflammatory compound, such as portulaca extract; or a fragrance such as cinnamon extract.

As discussed above, De Paoli teaches using a 5-alpha-reductase inhibitor, such as capryloyl glycine [0020], a glycine derivative for the treatment of acne.

Chan disclosed that portulaca extract has anti-inflammatory properties (abstract).

Malton teaches that cinnamon extract is a suitable fragrance used in cosmetic compositions (col. 3, line 7).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate capryloyl glycine, portulaca extract and cinnamon extract into Khaiat's composition. The person of ordinary skill in the art would have been motivated to make those modifications and reasonably would have expected success, because Khaiat teaches that the 5-alpha-reductase enzyme caused excess

sebum secretion (pg. 6, line 15-19); thus, suggesting the inhibition of the 5-alpha-reductase enzyme would decrease sebum secretion. In addition, Khaiat suggested, "any suitable topical anti-inflammatory agent can be used in accordance with this invention" (pg. 8, line 20-21) and "the compositions will contain other components, normally present in skin treatment compositions such as...fragrances" (pg. 9, line 8-12).

Telephonic Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jake M. Vu whose telephone number is (571) 272-8148. The examiner can normally be reached on Mon-Fri 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Art Unit 1618

MICHAEL HARTLEY
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